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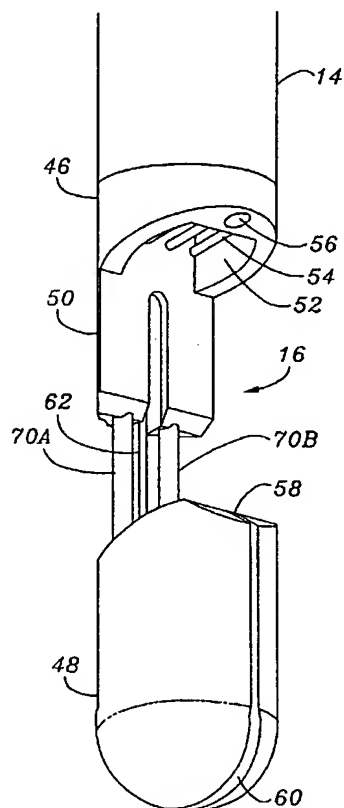
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[Continued on next page]

(54) Title: **MITRAL VALVE REPAIR DEVICE AND METHOD FOR USE**



(57) Abstract: A single catheter mitral valve repair device for stabilizing a tissue portion and selectively applying a tissue fastener thereto. The single catheter mitral valve repair device of the present invention includes an extendable engagement tip having at least one vacuum port formed thereon, at least one deployable fastener in communication with the engagement tip, and at least one actuator member in communication with the port. The deployable fastener is capable of controllably engaging and fastening a tissue segment located proximal to the engagement tip.

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MITRAL VALVE REPAIR DEVICE AND METHOD FOR USE

5 CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application discloses subject matter related to our co-pending United States Patent Application No. 09/562,406, filed May 1, 2000, entitled Minimally Invasive Mitral Valve Repair Method and Apparatus. The disclosure of the aforementioned United States patent
10 application is incorporated by reference herein in its entirety.

BACKGROUND OF THE INVENTION

[0002] In vertebrate animals, the heart is a hollow muscular organ having four pumping chambers: the left atrium, the left ventricle, the right atrium and the right ventricle. The atria are isolated from their respective
15 ventricles by one-way valves located at the respective atrial-ventricular junctions. These valves are identified as the mitral (or bicuspid) valve on the left side of the heart, and tricuspid valve on the right side of the heart. The exit valves from the left and right ventricles are identified as the aortic and pulmonary valves, respectively.

20 [0003] The valves of the heart are positioned in valvular annuluses that comprise dense fibrous rings attached either directly or indirectly to the atrial and ventricular muscle fibers. Valve leaflets comprising flexible collagenous structures are attached to, and extend inwardly from, the annuluses to meet at coapting edges. The aortic, tricuspid and
25 pulmonary valves each have three leaflets, while the mitral valve only has two. In normal operation, the leaflets of the mitral valve open as left ventricle dilates thereby permitting blood to flow from the left atrium into the left ventricle. The leaflets then coapt (i.e. close) during the contraction cycle of the left ventricle, thereby preventing the blood from
30 returning to the left atrium and forcing the blood to exit the left ventricle

through the aortic valve. Similarly, the tricuspid valve regulates flow from the right atrium into the right ventricle, and the pulmonary valve regulates blood exiting the right ventricle.

[0004] For a number of clinical reasons various problems with heart valves can develop. One common form of heart disease involves the deterioration or degradation of the heart valves, which leads to stenosis and/or insufficiency. Heart valve stenosis is a condition in which the valve does not open properly. Insufficiency is a condition in which the valve does not close properly. Insufficiency of the mitral valve, most common because of the relatively high fluid pressures in the left ventricle, results in mitral valve regurgitation ("MR"), a condition in which blood reverses its intended course and flows "backward" from the left ventricle to the left atrium during heart contractions.

[0005] A number of surgical techniques have been developed to repair degraded or otherwise incompetent heart valves. A common procedure involves replacement of a native aortic or mitral valve with a prosthetic heart valve. Such procedures require the surgeon to access the heart through the patient's chest (or possibly percutaneously), surgically remove the incompetent native heart valve and associated tissue, remodel the surrounding valve annulus, and secure a replacement valve in the remodeled annulus. While these procedures can be very effective, there are associated shortcomings. For example, the highly invasive nature of the implantation procedure typically results in substantial patient discomfort and requires patients to remain hospitalized for extended recovery periods. In addition, the two basic types of commercially available replacement valves, mechanical valves, and tissue valves, have shortcomings of their own. Mechanical replacement valves typically offer extended operational lifetimes, but the patient is usually required to maintain a regimen of anti-coagulant drugs

for the remainder of his or her life. Tissue valves typically offer a higher degree of acceptance by the body thereby reducing or eliminating the need for anti-coagulants, but the operational lifetimes of tissue valves is typically shorter than mechanical valves and thus may require a subsequent replacement(s).

[0006] As an alternative to prosthetic heart valve replacement, it is often preferable to remodel the native heart valve and/or surrounding tissue. Remodeling procedures often preserve left ventricular function better than mitral valve replacement because the subvalvular papillary muscles and chordae tendineae are preserved (most prosthetic valves do not utilize these muscles). Typically, valvular remodeling is accomplished by implanting a prosthetic ring ("annuloplasty ring") into the valve annulus to reduce and/or stabilize the structure of the annulus. Annuloplasty rings are typically constructed of a resilient core covered with a fabric sewing material. Annuloplasty procedures can be performed alone, or they can be performed in conjunction with other procedures such as leaflet repair. Although annuloplasty procedures have become popular and well accepted, reshaping the surrounding annulus and traditional leaflet repairs do not always lead to optimum leaflet coaptation. As a result, some patients may still experience residual mitral valve regurgitation following annuloplasty procedures.

[0007] A recently developed technique known as a "bow-tie" repair has also been advocated for repairing insufficient heart valves, in particular the mitral valve. The mitral valve bow-tie technique involves, in its simplest form, suturing the anterior and posterior leaflets together near the middle of their coapting edges, thereby causing blood to flow through two newly formed side openings. While this does reduce the volume of blood that flows from the atrium to the ventricle, this loss is more than compensated by improved leaflet coaptation, which reduces

mitral regurgitation. As originally developed by Dr. Ottavio Alfieri, this process involved arresting the heart, and placing the patient on extra corporeal bypass and required invasive surgery to access and suture the leaflets together. More recently, however, some have advocated a
5 "beating heart" procedure in which the leaflets are accessed remotely and the heart remains active throughout the procedure.

[0008] A particular method for performing a beating heart bow-tie procedure (i.e. without extra corporeal bypass) has been proposed by Dr. Mehmet Oz, of Columbia University. The method and devices for
10 performing the method are described in PCT publication WO 99/00059, published January 7, 1999. In one embodiment of the disclosed procedure, the associated device consists of a forceps-like grasper used to grasp and hold the mitral valve leaflets in a coapted position for suturing. Since the mitral valve leaflets meet and curve toward and
15 slightly into the left ventricular cavity at their mating edges, the grasper device is passed through a sealed aperture in the apex of the left ventricle. The edges of the mating mitral valve leaflets are then grasped and held together, and a fastening device such as a clip or suture is utilized to fasten them. The fastening device should be applied to the
20 leaflet tissue with sufficient tissue purchase to prevent tear out or other failure, but close enough to the edges to ensure that the newly created side holes are as large as possible. The Mehmet Oz disclosure thus illustrates that teeth of the grasper device can be linearly slidable with respect to one another so as to permit alignment of the mitral valve
25 leaflets prior to fastening. Since the procedure is done on a beating heart, it will be readily understood that the pressures and motions within the left ventricle and mitral valve leaflets are severe. Thus the procedure taught by Dr. Mehmet Oz is very skill-intensive.

[0009] The bow-tie technique has proved to be a viable alternative for treating otherwise incompetent heart valves. Nonetheless, several shortcomings associated with current bow-tie procedures have been identified. Current systems include devices having mechanical
5 graspers, barbed members, and vacuum devices that simultaneously capture and retain the valve leaflets prior to applying a fastening device thereto. Often, use of these devices results in the less than optimal leaflet stabilization and fastener placement. Many of these problems arise from the fact that the surgeon is required to capture, retain and
10 fasten the leaflets in one relatively inflexible procedure. These difficulties are compounded when the leaflets are small or calcified making them difficult to pull together, and in beating heart procedures in which the leaflets are actively functioning throughout the surgery. In light of the foregoing, there is presently a need for improved systems for
15 stabilizing multiple tissue heart valve leaflets and placing a fastening device there between. More specifically, there is a present need for an improved bow-tie procedure for repairing a patient's mitral valve.

BRIEF SUMMARY OF THE INVENTION

20 [0010] The single catheter mitral valve repair device of the present invention may be used to repair tissue throughout a patient's body. However, it is particularly useful in repairing dysfunctional mitral valve tissue by stabilizing discrete valvular tissue pieces and deploying a fastening device therethrough, thereby coapting the tissue pieces. The
25 present invention may also be used to repair arterial septal defects (ASD), ventricular septal defects (VSD), and defects associated with patent foramen ovale (PFO).

[0011] In one aspect, the repair device of the present invention comprises an extendable engagement tip having at least one port

formed thereon, at least one deployable fastener in communication with the engagement tip, and one or more actuator members in communication with the port(s). The deployable fastener is capable of controllably engaging and fastening tissue located proximal to the engagement tip.

[0012] In another aspect of the present invention, the repair device comprises a handle, an elongated body, and an extendable engagement tip. The handle comprises a stationary handle body, an engagement tip actuator in communication with the stationary handle body, a fastener deployment housing in communication with the stationary handle body, and a vacuum connector capable of placing a vacuum source in communication with the stationary handle body. The elongated body comprises a flexible body member, at least one vacuum lumen, one or more actuation lumens and one or more fastener lumens. Optionally, the elongated body can also comprise one or more auxiliary lumens. The one or more actuation lumens are capable of receiving one or more actuation members therein. Similarly, the one or more fastener lumens are capable of receiving at least one deployable fastener therein. The extendable engagement tip comprises a fastener deployment housing capable of attaching to the elongated body, an actuation flange attached to the fastener deployment housing, an extendable tip attached to the actuation flange and in communication with the engagement tip actuator, a vacuum port in communication with the vacuum connector, and at least one deployable fastener in communication with the fastener deployment housing.

[0013] The present invention also discloses a method of repairing tissue using the repair device of the present invention and comprises grasping a first tissue portion with a vacuum force, stabilizing the first tissue portion with a mechanical force, deploying a tissue fastener into

the stabilized first tissue portion, disengaging the first tissue portion, grasping at least a second tissue portion with a vacuum force, stabilizing at least a second tissue portion with a mechanical force, deploying at least a second tissue fastener into at least the second stabilized tissue portion, disengaging at least the second tissue portion, and coapting the first tissue portion and at least the second tissue portion with the first tissue fastener and at least the second tissue fastener.

[0014] Other objects, features, and advantages of the present invention will become apparent from a consideration of the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The apparatus of the present invention will be explained in more detail by way of the accompanying drawings, wherein:

[0016] Fig.1 shows a perspective view of the mitral valve repair device of the present invention;

[0017] Fig. 2 shows a perspective view of the handle portion of the mitral valve repair device of the present invention;

[0018] Fig. 3 shows a cross-sectional view of the handle portion of the mitral valve repair device of the present invention;

[0019] Figs. 4A and 4B show alternate cross-sectional views of the elongated body of the mitral valve repair device of the present invention;

[0020] Figs. 5A and 5B show alternate perspective views of the engagement tip of the mitral valve repair device of the present invention;

[0021] Fig. 6 shows a cross-sectional view of the engagement tip of the mitral valve repair device of the present invention;

[0022] Figs. 7A and 7B show alternate perspective views of the engagement tip of the mitral valve repair device of the present invention
5 in an extended position;

[0023] Fig. 8 shows a cross-sectional view of the engagement tip of the mitral valve repair device of the present invention in a retracted position wherein the deployable needle is deployed;

[0024] Fig. 9 shows a cross-sectional view of the engagement tip of the mitral valve repair device of the present invention in a retracted
10 position wherein the deployable needle is retracted and is engaging a needle catch;

[0025] Fig. 10 shows a perspective view of the mitral valve repair device of the present invention having attached fastener material to a
15 first tissue portion;

[0026] Fig. 11 shows a perspective view of the mitral valve repair device of the present invention having attached fastener material to a second tissue portion;

[0027] Fig. 12 shows a perspective view of discrete tissue portions
20 having fastener material positioned therethrough; and

[0028] Fig. 13 shows a perspective view of discrete tissue portions being coapted with fastener material.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0029] Disclosed herein is a detailed description of various embodiments of the present invention. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the invention. The overall organization of the description is for the purpose of clarity only and is not intended to limit the present invention.

[0030] The single catheter mitral valve repair device of the present invention is designed for use in a surgical treatment of bodily tissue. As those skilled in the art will appreciate, the exemplary single catheter mitral repair device disclosed herein is designed to minimize trauma to the patient before, during, and after a minimally invasive surgical procedure while providing improved tissue stabilization and enhanced placement of a fastening device thereon. While the single catheter mitral valve repair device of the present invention may be used to repair tissue throughout a patient's body, it is particularly useful in repairing dysfunctional mitral valve tissue by stabilizing discrete valvular tissue pieces and deploying a fastening device therethrough, thereby coapting the tissue pieces. The present invention may also be used to repair arterial septal defects (ASD), ventricular septal defects (VSD), and defects associated with patent foramen ovale (PFO).

[0031] Figure 1 shows the single catheter mitral valve repair device of the present invention. As shown, the repair device 10 comprises a handle portion 12 attached to an elongated body 14. An engagement tip 16 is positioned on the distal portion of the elongated body 14. A vacuum connector 18 is attached to the handle 12. As those skilled in the art will appreciate, the present invention may be manufactured from a variety of materials including, without limitation, various metals, plastics, thermoplastics, silicones, elastomers, ceramics, composite

materials, or various combinations of the aforementioned materials. For example, the handle 12 may be manufactured from polyethylene, while the elongated body 14 is manufactured by an elastomer. In an alternate embodiment the elongated body 14, the engagement tip 16, or both may incorporate radio-opaque or echogenic materials, thereby enabling the surgeon to precisely position the repair device 10 within the patient's body.

[0032] Figure 2 shows a perspective view of the handle 12 of the present invention. As shown in Figure 2, the handle 12 comprises a stationary handle body 20 having a tip actuator 22 and a fastener deployment actuator 24 in communication therewith. The tip actuator 22 and fastener deployment actuator 24 are movable relative to the stationary handle body 20. Exemplary tip actuator members or fastener deployment housings may include, for example, buttons, levers, slidable fixtures, or toggles. The distal portion of the stationary handle body 20 includes a coupling orifice 26 capable of receiving the elongated body 14 therein. In addition, the stationary handle body 20 may include a handle flange 28 located thereon. The stationary handle body 20, fastener deployment actuator 24, or tip actuator 22, may include at least one grip member 30 positioned thereon. As shown in Figure 2, a vacuum connector 18 is in communication with the handle 12.

[0033] Figure 3 shows a cross sectional view of the handle 12 of the present invention. As shown in Figure 3, the stationary handle body 20 defines an actuation channel 32, which is in communication with the coupling orifice 26 formed on the distal portion of the stationary handle body 20. The actuation channel 32 formed inside the stationary handle body 20 is capable of receiving the tip actuator 22 and the fastener deployment actuator 24 independently and in telescoping relation therein. Those skilled in the art will appreciate that the present invention

permits a user to actuate the tip actuator 22 or the fastener deployment actuator 24 independently. As shown, a bias member 34 may be positioned within the actuation channel 32 and may communicate in biasing relation with the fastener deployment actuator 24. The tip actuator 22 is in communication with at least one actuator extension member (see Fig. 7) positioned within one or more actuation lumens (see Fig. 4) formed in the elongated body 14. Similarly, the fastener deployment actuator 24 is in communication with at least one fastener extension member (see Fig. 6) positioned within one or more fastener lumens (see Fig. 4) formed in the elongated body 14. The vacuum connector 18 is to be connected to an external vacuum source and is in fluid communication with the vacuum lumen 36 formed in the elongated body 14.

[0034] The elongated body 14 of the present invention may be manufactured in a variety of lengths or diameters as desired by the user. Figures 4A and 4B show cross-sectional views of two embodiments of the elongated body 14 of the present invention. As shown in Figure 4, the elongated body 14 of the present invention may comprise at least one vacuum lumen 36. In the illustrated embodiment, the vacuum lumen 36 is disposed in the center of the device; although those skilled in the art will appreciate that the present invention may be easily manufactured with the vacuum lumen 36 positioned at various locations within or alongside the elongated body 14. The body member 38 may further include one or more tip actuation lumens 40a, 40b, one or more auxiliary lumens 42, and one or more fastener lumens 44 formed therein. For example, Figure 4B shows an alternate embodiment of the present invention wherein the body member 38 forms a vacuum lumen 36, tip actuation lumens 40a, 40b, auxiliary lumens 42, and two fastener lumens 44a, 44b therein. Those skilled in the art will appreciate that the

one or more auxiliary lumens 42 of the present invention are capable of receiving a guidewire, thereby enabling the present invention to be directed to an area of interest in vivo with a guidewire. The elongated body 14 of the present invention may be attached to the handle 12 in a variety of manners, including, for example, adhesively attached or in snap-fit relation.

[0035] Figure 5A shows a perspective view of the engagement tip 16 attached to the elongated body 14 of the present invention. The engagement tip 16 comprises a fastener deployment housing 46, an extendable tip 48, and an actuation flange 50 in communication with the fastener deployment housing 46 and the extendable tip 48. The fastener deployment housing 46 further includes at least one vacuum port 52 having a tissue support 54 located therein, and a fastener deployment port 56 located thereon. The tissue support 54 may comprise a series of vanes or other supports positioned across or proximate to the vacuum port 52. The vacuum port 52, positioned on the fastener deployment housing 46, is in fluid communication with the vacuum connector 18 positioned on the handle 12 through the vacuum lumen 36 formed in the elongated body 14. Similarly, the fastener deployment port 56 is in communication with the fastener deployment actuator 24 located on the handle 12 through fastener lumen 44 formed in the elongated body 14. In an alternate embodiment illustrated in Figure 5B, a plurality of fastener deployment ports 56 may be formed on the fastener deployment housing 46 and may be in communication with a plurality of fastener lumens 44 formed in the elongated body 14 (see Figure 4B). The extendable tip 48 of the present invention is in communication with the tip actuator 22 located on the handle 12 through the actuation lumens 40a, 40b formed in the elongated body 14. The extendable tip 48 may include a fastener receiver port 58 capable of receiving the

deployable needle 64 therein (see Fig. 6). The fastener receiver port 58 is coaligned with or positioned proximate to the fastener deployment port 56 formed on the fastener deployment housing 46. The fastener receiving port 58 is capable of receiving the deployable needle 64 therein and includes a needle catch 68 attached to fastener material 62 (see Fig. 6). The needle catch 68 may comprise a variety of devices capable of engaging and retaining the deployable needle 64 therein, including, for example, a ferruled or sized ring. In addition, the extendable tip 48 may include a fastener channel 60 capable of receiving fastener material 62 therein. Preferably the fastener channel 60 is open on the distal end of extendable tip 48, as illustrated. Exemplary fastener materials include, for example, thread, wire, monofilament, braided filament, suture material, needles, sutures, staples, buttons, tissue-graspers, tissue clasps, barbs, and other tissue-coaption devices.

[0036] Figure 6 shows a cross sectional view of the engagement tip 16. The vacuum port 52 is in fluid communication with the vacuum lumen 36. A deployable needle 64 is in communication with the deployment housing 66 positioned within the fastener lumen 44. The receiver port 58 is in communication with the auxiliary lumen 42 located in the elongated body 14. A needle catch 68, which is capable of engaging and retaining the deployable needle 64, is attached to fastener material 62 which is positioned within the receiver port 58 and which extends through the auxiliary lumen 42 around the distal end of the engagement tip 16 and back towards the handle 12.

[0037] Figures 7A and 7B show the engagement tip 16 of the present invention in an extended configuration, thereby enabling the present invention to grasp and stabilize tissue located proximate thereto with a vacuum force. As shown in Figure 7A, actuation members 70a,

70b are slidably received in the fastener deployment housing 46 and the extendable tip 48, thereby permitting the extendable tip 48 to be moved, in telescoping relation, relative to the fastener deployment housing 46. Exemplary actuation members 70a, 70b may include, for example, rods, shafts, or conduits. The actuation members 70a, 70b communicate with the tip actuator 22 positioned on the handle 12 through the actuation lumens 40a, 40b positioned in the elongated body 14. To actuate the extendable tip 48, the user advances the tip actuator 22 towards the stationary handle body 20, thereby advancing the actuation members 70a, 70b and resulting in the extendible tip 48 extending from the fastener deployment housing 46. To retract the extendible tip 48, the user retracts the tip actuator 22 away from the stationary handle body 20, thereby retracting the actuation members 70a, 70b and resulting in the extendible tip 48 retracting towards the fastener deployment housing 46. Those skilled in the art will appreciate that actuation of the tip actuator 22 results in the longitudinal movement of the actuation member 70a, 70b positioned in the tip actuator lumens 40a, 40b of the elongated body 14, thereby resulting in the longitudinal extension and retraction of the extendable tip 48. Figure 7B shows and alternate embodiment in which there are a plurality (two in the illustrated case) of deployment ports 56, fastener receiver ports 58 and corresponding fastener channels 60. Figure 7B illustrates another alternate embodiment in which the faster material is stored within the vacuum lumen 36 (as opposed to the auxiliary lumen 42, see figure 6).

[0038] Figures 8 and 9 show cross sectional views of the engagement tip 16 of the present invention during use wherein a mechanical stabilization force may be applied to captured tissue. Figure 8 shows a cross sectional view of the engagement tip 16 wherein the deployable needle 64 has been deployed from the fastener deployment

port 56 located on the fastener deployment housing 46 through the fastener receiver port 58 and into the extendable tip 48. The deployable needle 64 is attached to the deployment housing 66 positioned within the one or more fastener lumens 44 of the elongated body 14. The deployment housing 66 is coupled to the fastener deployment actuator 24 positioned on the handle 12. To deploy the deployable needle 64, the user advances the fastener deployment actuator 24 on the handle 12 towards the stationary handle body 20, which results in the longitudinal movement of the deployment housing 66 within the fastener lumen 44 of the elongated body 14. Longitudinal movement of the deployment housing 66 results in the deployable needle 64 advancing through the fastener deployment port 56 into the fastener receiving port 58 and engaging the needle catch 68 located therein. As shown in Figure 8, the deployable needle 64 has engaged the needle catch 68. The needle catch 68 is attached to the fastener material 62 located within the auxiliary lumen 42.

[0039] Figure 9 shows a cross sectional view of the engagement tip 16 of the present invention wherein the deployable needle 64, having engaged and been retained by the needle catch 68 attached to the fastener material 62, is positioned within the fastener lumen 44 of the elongated body 14. To retract the deployable needle, the user moves the fastener deployment actuator 24 rearwardly away from the stationary handle body 20. As a result, the deployment housing 66 moves in a reward longitudinal motion which results in the deployable needle 64, which is attached to the deployment housing 66, moving rearwardly. The deployable needle 64, having the needle catch 68 and the fastener material 62 attached thereto, retracts through the fastener receiving port 58 and enters the fastener deployment port 56. As shown in Figure 9, the fastener material 62 is in communication with the auxiliary lumen 42

and the fastener lumen 44, thereby traversing the actuation flange 50. In an alternate embodiment of the present invention the extendable tip 48, the fastener deployment housing 46, or the elongated body 14 may include at least one guidewire retaining device or lumen therein or attach thereto. In yet another alternate embodiment, the positions of the needles and needle catch are reversed (i.e. the needle moves from the extendable tip 48 to engage the needle catch in the port 56).

[0040] The present invention also discloses a method of using the single catheter mitral valve repair device of the present invention to repair discreet tissue portions in vivo. The description below describes a method of repairing dysfunctional heart valves, however, those skilled in the art will appreciate that the present invention may be adapted for use in other tissue repair procedures.

[0041] To repair a dysfunctional or otherwise incompetent heart valve, a guidewire capable of traversing the circulatory system and entering the heart of the patient is introduced into the patient through an endoluminal entry point. For example, an endoluminal entry point may be formed in a femoral vein or right jugular vein of a patient. Thereafter, the guidewire may be introduced into the patient through the endoluminal entry point and advanced through the circulatory system, eventually arriving at the heart. Upon arriving at the heart, the guidewire is directed into the right atrium of the heart, traverses the right atrium and is made to puncture the atrial septum, thereby entering the left atrium. The guidewire may then be advanced through the mitral valve while the heart is in diastole and traverses the left ventricle. The guidewire traverses the aortic valve into the aorta and is made to emerge from the left femoral artery through an endoluminal exit point. This methodology of positioning a guidewire is known to physicians skilled in the art of interventional cardiology. Once the guidewire is

positioned, the endoluminal entry or exit port is dilated to permit entry of a catheter therethrough. A protective sheath may be advanced in the venous area to protect the vascular structure.

[0042] With the guidewire suitably anchored, the distal portion of the mitral valve repair device of the present invention may be attached to the guidewire. Thereafter, the elongated body 14 having the engagement tip 16 attached thereto is advanced through the dilated guidewire entry port to a point proximate the cusp portion of the mitral valve. Those skilled in the art will appreciate that the mitral valve repair device 10 of the present invention may approach the cusp of the mitral valve from an antegrade position or from a retrograde position as desired by the user. For a retrograde approach, the user attaches the repair device 10 to the guidewire emerging from the left femoral artery. The device is then advanced along the guidewire to a position proximate the retrograde aspect of the mitral valve. The engagement tip 16 of the mitral valve repair device 10 may be positioned proximate the tissue portion 72 of the mitral valve. Once suitably positioned, the tip actuator 22 positioned on the handle 12 may be actuated, thereby resulting in the extendable tip 48 of the engagement tip 16 extending distally from the fastener deployment housing 46. Thereafter, an external vacuum source (not shown) may be activated to apply a vacuum force to the mitral valve repair device 10 through the vacuum connector 18. The external vacuum source (not shown) communicates with the vacuum port 52 located on the engagement tip 16 through the at least one vacuum lumen 36 in the elongated body 14. With the extendable tip 48 distally extended from the fastener deployment housing 46, the tissue portion 72 located proximate to the vacuum port 52 is grasped and retained by the vacuum force applied by the external vacuum source (not shown). Once the tissue portion 72 is captured by the vacuum force supplied through

the vacuum port 52, the tip actuator 22 located on the handle 12 is actuated to retract the extendable tip 48 toward the fastener deployment housing 46 thereby mechanically retaining and stabilizing the tissue portion 72 therebetween. Once the tissue is sufficiently stabilized, the fastener deployment actuator 24 located on the handle 12 may be actuated to deploy a fastening device through the tissue portion 72. To deploy the fastener device the user advances the fastener deployment actuator 24 toward the handle flange 28 positioned on the stationary handle body 20 of the handle 12, thereby causing the deployable needle 64 to exit the deployment port 56 and traverse the tissue positioned within the actuation flange 50. Thereafter, the deployable needle 64 enters the receiver port 58 formed on the extendable tip 48 and engages the needle catch 68 which is attached to the fastener material 62 positioned within the fastener channel 60. The fastener deployment housing 46 is returned to a non-deployed position by the user, thereby resulting in the deployable needle 64, which has retained the needle catch 68 attached to the fastener material 60, returning to a non-deployed position within the fastener lumen 44 of the elongated body 14, and resulting in the tissue portion 72 having fastener material 62 positioned therethrough. As shown in Figure 10, with the fastener material 62 positioned through the tissue portion 72, the external vacuum source may be deactivated which results in the release of the captured tissue portion 72. Thereafter, the mitral valve repair device 10 of the present invention is removed from the patient's body leaving a fastener material 62 attached to the tissue portion 72.

[0043] Once removed from the body of the patient, the mitral valve repair device 10 may be reloaded with deployable need and fastener material, rotated, and reintroduced into the patient thereby permitting the device to apply additional tissue fasteners to bodily tissue adjacent that

already fastened. At least the distal portion of the mitral valve repair device of the present invention is re-attached to the guidewire. Thereafter, the elongated body 14 having the engagement tip 16 attached thereto is again advanced through the dilated guidewire entry port to a point proximate the cusp portion of the mitral valve. The engagement tip 16 of the mitral valve repair device 10 may be positioned proximate to another tissue portion 74 of the mitral valve. The preceding process is then repeated to secure suture material 62' to tissue portion 74. Figure 11 shows the mitral valve repair device 10 positioned proximate to a second tissue portion 74 located near the first tissue portion 72. As shown, the fastener material 62' is positioned through the tissue portion 74 and the external vacuum source may be deactivated which results in the release of the captured tissue portion 74. Thereafter, the mitral valve repair device 10 of the present invention is removed from the patient's body and may be removed from the patient's body leaving a fastener material 62' attached to the tissue portion 74. Thereafter, the fastener material portions 62, 62' may be joined to coapt the individual tissue portions 72, 74. As shown in Figure 12-13, a knot 76 is formed in the fastener material 62, 62' and advanced to the tissue portions 72, 74. In one embodiment, the knot 76 is formed external the patient's body and advanced to the repair site with a knot-pushing device.

[0044] In the alternative embodiments of figures 4B, 5B and 7B, the repair device need not be removed from the patient between the steps of securing the first and second tissue pieces. The dual fastening system of these alternate embodiments permits the faster material to be placed sequentially in both pieces of tissue simply by rotating the device after securing the first piece of tissue. Lastly, one of skill in the art will understand that if the vacuum source is strong enough, and the needle

64 sharp enough, extendable tip 64 need not translate relative to the deployment housing 46 to mechanically hold the tissue in place. The pieces of tissue can be held together in place with vacuum and punctured without use of mechanical retention.

- 5 [0045] In closing, it is understood that the embodiments of the invention disclosed herein are illustrative of the principals of the invention. Other modifications may be employed which are within the scope of the present invention. Accordingly, the present invention is not limited to that precisely as shown and described in the present
10 disclosure.

What is claimed is:

1. An apparatus for fastening a tissue segment within the heart of a patient in vivo, comprising:
 - 5 an elongated body having a proximal end and a distal end;
a fastener deployment housing at the distal end of the elongated body, the fastener deployment housing having at least one vacuum port and at least one fastener deployment port formed thereon;
an extendable engagement tip capable of moving in
10 telescopic relation to the fastener deployment housing, the extendable engagement tip having at least one fastener receiving port formed thereon;
at least one deployable fastener disposed within the fastener deployment housing, the deployable fastener capable of
15 engaging the tissue segment when positioned proximal to the engagement tip; and
at least one fastener deployment actuator in communication with the deployable fastener and capable of causing the fastener to engage the tissue segment.
- 20 2. The apparatus of claim 1 wherein the engagement tip further comprises:
 - an actuation flange that telescopically couples the fastener deployment housing with the extendable tip.
3. The apparatus of claim 2 further comprising an extendable
25 tip actuator in communication with the extendable tip, wherein the extendable tip actuator is capable of causing the extendable tip to move in telescopic relation to the fastener deployment housing.
4. The apparatus of claim 1 wherein the vacuum port and fastener port are one in the same.

5. The apparatus of claim 1 further comprising multiple vacuum ports formed on the fastener deployment housing.

6. The apparatus of claim 1 wherein the vacuum port further comprises at least one tissue support traversing the vacuum port.

5 7. The apparatus of claim 1 wherein the at least one fastener deployment port is capable of receiving the deployable fastener therein.

8. The apparatus of claim 1 wherein the fastener receiving port is capable of receiving the deployable fastener therein.

9. The apparatus of claim 1 wherein the fastener receiving
10 port further comprises at least one fastener catch the capable of engaging and retaining the deployable fastener.

10. The apparatus of claim 9 wherein the fastener catch is in communication with a fastener material.

11. The apparatus of claim 10 wherein the fastener material is
15 selected from the group consisting of thread, wire, monofilament, braided filament, and suture material.

12. The apparatus of claim 1 wherein the deployable fastener is selected from the group consisting of a needles, sutures, staples, buttons, tissue-graspers, tissue clasps, and barbs.

20 13. The apparatus of claim 1 further comprising a handle in communication with the engagement tip.

14. The apparatus of claim 13 wherein the handle comprises a engagement tip actuator in communication with the engagement tip, a fastener deployment actuator in communication with the deployable
25 fastener, and a vacuum actuator in communication with the vacuum port.

15. The apparatus of claim 1 wherein the elongated body is flexible.

16. The apparatus of claim 15 wherein the elongated body contains one or more actuation members therein.

17. The apparatus of claim 16 wherein each actuation member is in communication with at least one device selected from the group consisting of the engagement tip, the port, the deployable fastener, the actuator, the handle, and an external vacuum source.

5 18. The apparatus of claim 17 wherein the external vacuum source is in communication with at least one vacuum lumen located within the elongated body, wherein the vacuum lumen communicates with the actuation members and the vacuum port.

10 19. The apparatus of claim 1 further comprising at least one lumen formed within the elongated body.

20. The apparatus of claim 19 wherein the auxiliary lumen is capable of receiving at least one device therein, the device selected from the group consisting of a fastener, fastener material, and a guidewire.

15 21. A system for repairing tissue within the body of a patient, comprising

 a handle comprising:

 a stationary handle body;

 a engagement tip actuator connected to the stationary handle body;

 a fastener deployment actuator coupled to the stationary handle body; and

 a vacuum connector;

 an elongated body comprising:

 a flexible body member;

 at least one vacuum lumen integral with the body member;

 at least one actuation lumen integral with the body member, wherein the actuation lumen is

capable of receiving at least one actuation member therein; and
at least one fastener lumen integral with the body member, wherein the fastener lumen is
5 capable of receiving at least one deployable fastener therein; and,
an engagement tip comprising:
a fastener deployment housing capable of attaching to the elongated body;
10 an actuation flange attached to the fastener deployment housing;
an extendable tip attached to the actuation flange and in communication with the engagement tip actuator;
15 a vacuum port in communication with the vacuum connector; and,
at least one deployable fastener in communication with the fastener deployment actuator.

22. A method of repairing tissue within the heart of a patient in
20 vivo, comprising:
grasping a first tissue portion with a vacuum force;
stabilizing the first tissue portion with a mechanical force;
deploying a tissue fastener into the stabilized first tissue
portion;
25 disengaging the first tissue portion;
grasping a second tissue portion with a vacuum force;
stabilizing the second tissue portion with a mechanical
force;

deploying a second tissue fastener into the second
stabilized tissue portion;

disengaging the second tissue portion; and

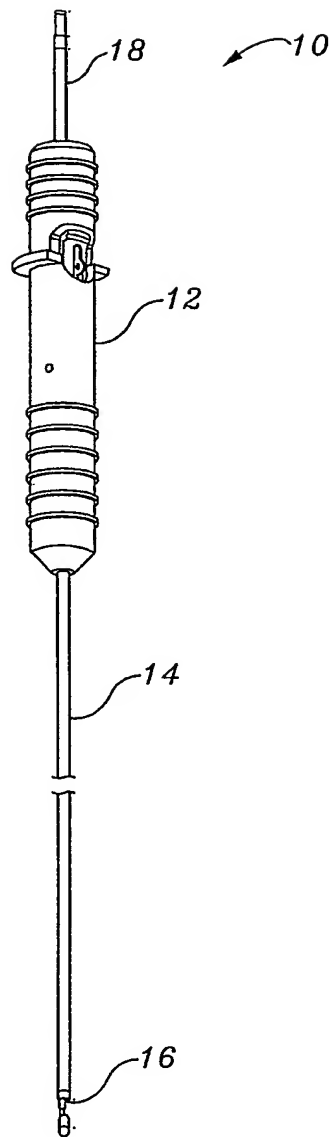
coapting the first tissue portion and the second tissue

5 portion by coupling the first and second tissue fasteners.

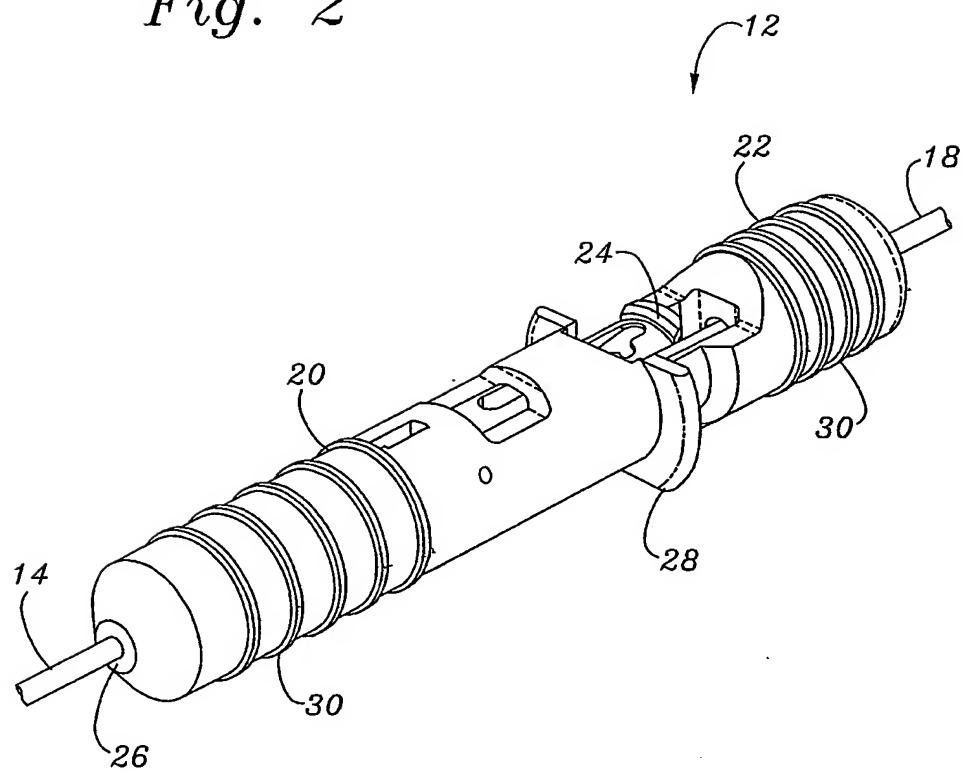
23. The method of claim 22 further comprising coapting the
first and second tissue portions with sutures.

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Fig. 1

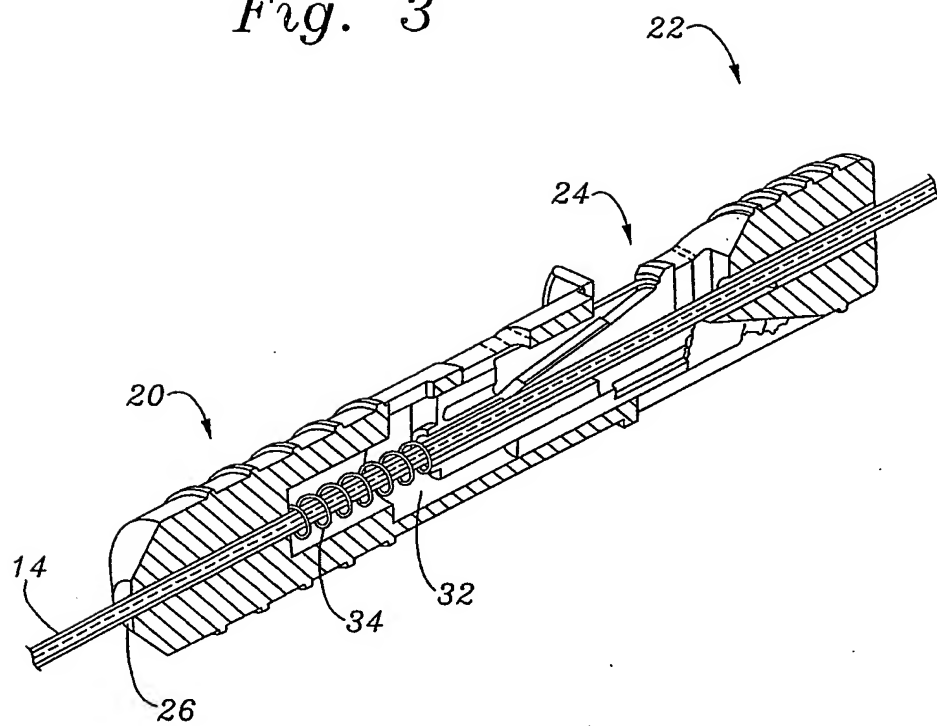


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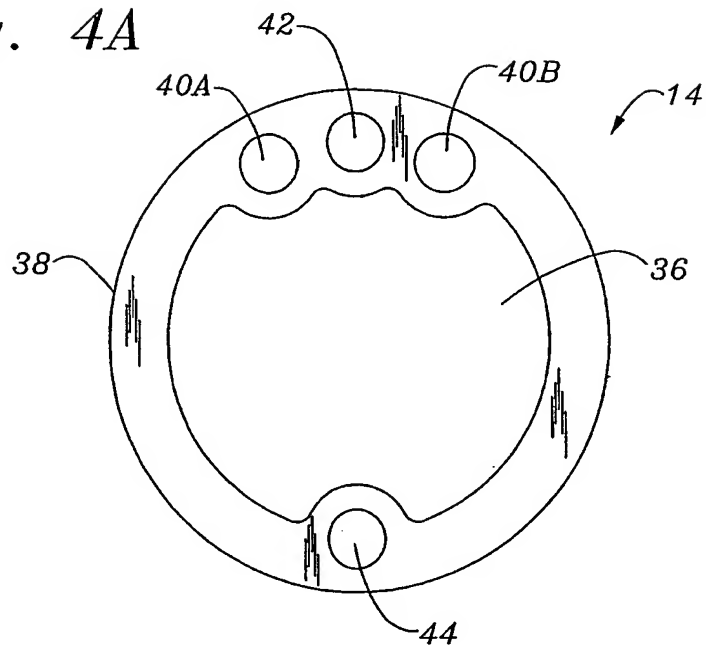
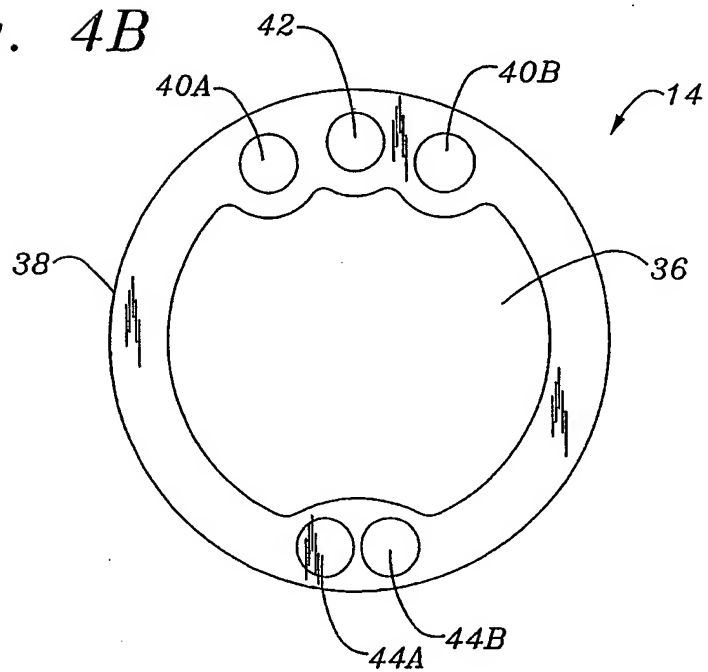
Fig. 2

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Fig. 3



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Fig. 4A*Fig. 4B*

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Fig. 5A

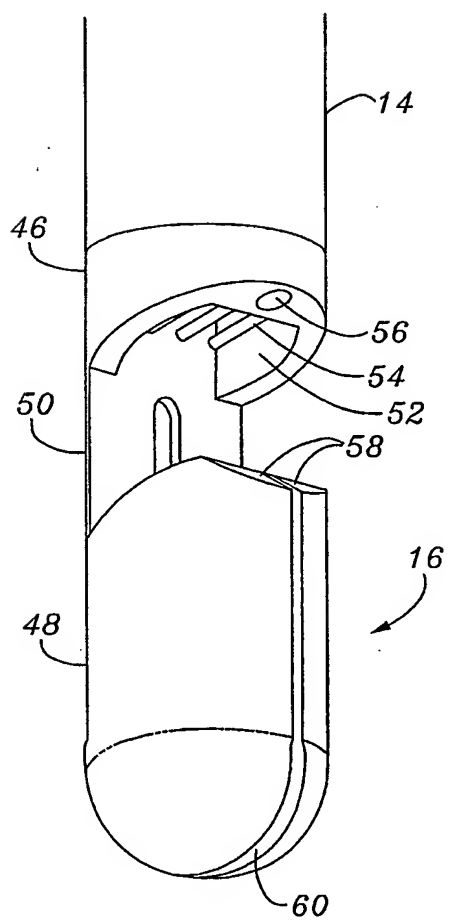
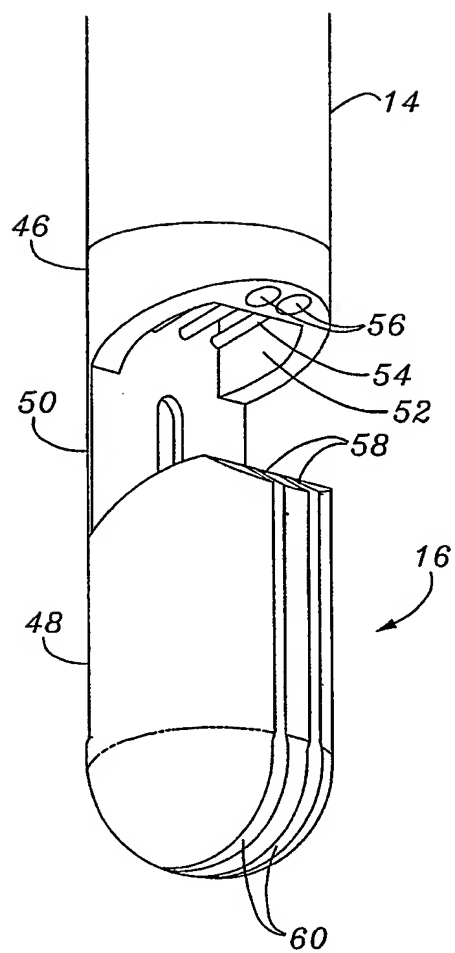
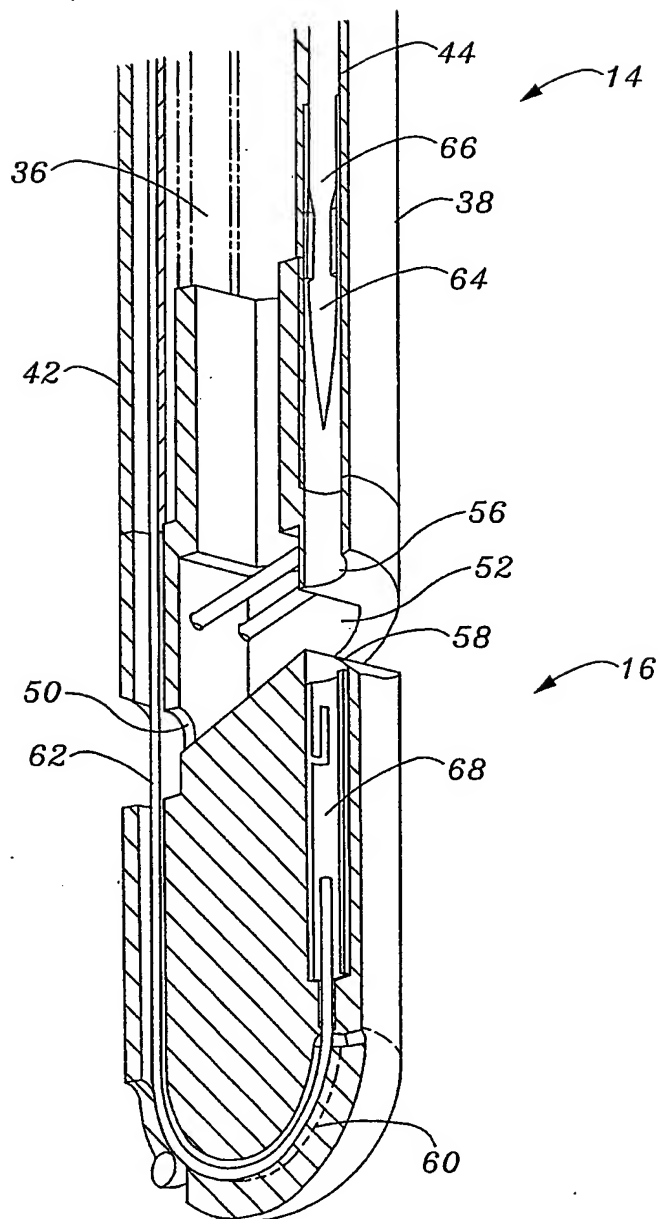


Fig. 5B



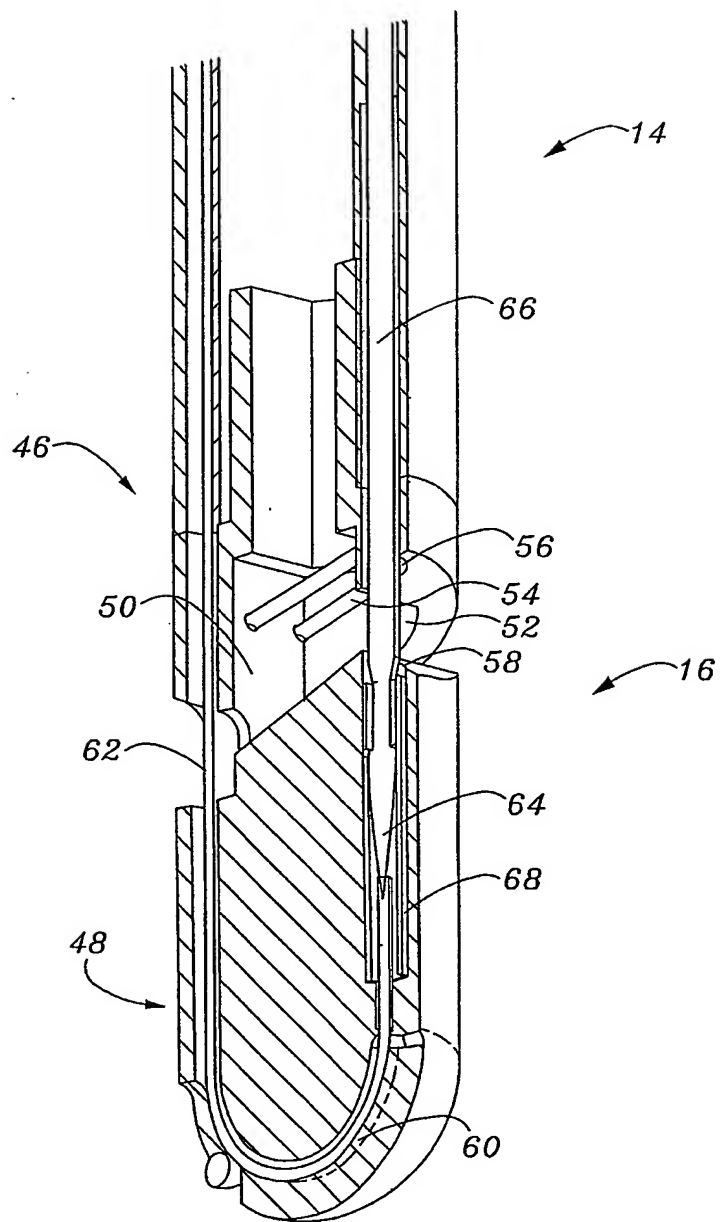
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Fig. 6



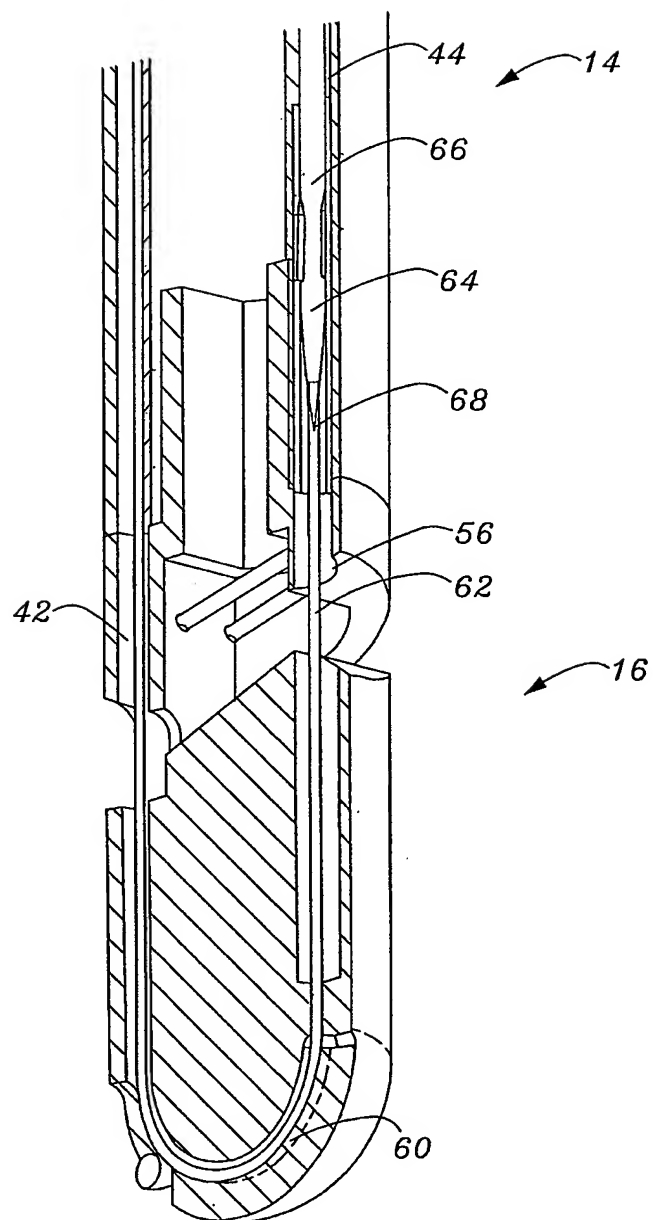
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Fig. 8



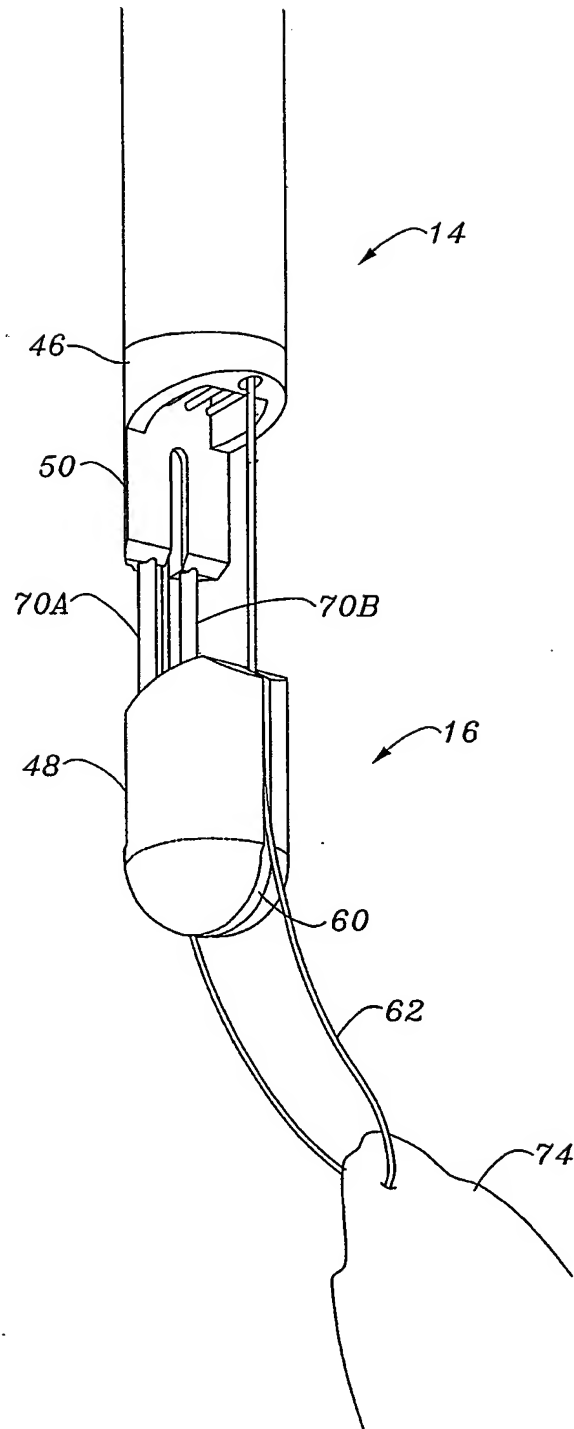
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Fig. 9



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Fig. 10



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Fig. 12

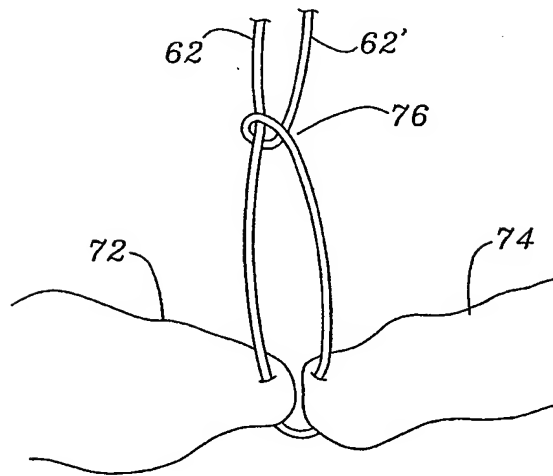
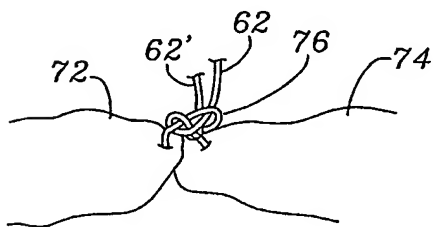


Fig. 13



INTERNATIONAL SEARCH REPORT

Internat application No

PCT/US 03/27661

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02 24078 A (OPUS MEDICAL, INC.) 28 March 2002 (2002-03-28) abstract; figures page 21, line 19 -page 24, line 29 ---	1-15, 19-21
Y	WO 95 25468 A (UNIVERSITY COLLEGE LONDON) 28 September 1995 (1995-09-28) abstract; figures page 4, line 25-28 ---	1-15, 19-21
A	WO 97 27807 A (HEARTPORT, INC.) 7 August 1997 (1997-08-07) page 33, line 8 -page 34, line 6; figures 34,35 ---	1,21
A	US 5 766 183 A (SAUER) 16 June 1998 (1998-06-16) abstract; figures -----	1,21



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

7 January 2004

Date of mailing of the international search report

15/01/2004

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INTERNATIONAL SEARCH REPORT

Int

application No.
PCT/US 03/27661

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 22, 23
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
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Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

9)
INTERNATIONAL SEARCH REPORT

Information on patent family members

Internati

cation No

PCT/US 03/27661

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0224078	A	28-03-2002	US 6551330 B1	22-04-2003
			AU 9505001 A	02-04-2002
			WO 0224078 A1	28-03-2002
			US 2003181925 A1	25-09-2003
WO 9525468	A	28-09-1995	AU 3245995 A	09-10-1995
			DE 69509641 D1	17-06-1999
			DE 69509641 T2	16-09-1999
			EP 0751745 A1	08-01-1997
			WO 9525468 A1	28-09-1995
			JP 10500318 T	13-01-1998
			US 5792153 A	11-08-1998
WO 9727807	A	07-08-1997	US 5860992 A	19-01-1999
			AU 1754097 A	22-08-1997
			WO 9727807 A1	07-08-1997
US 5766183	A	16-06-1998	US 6368334 B1	09-04-2002
			US 2002123756 A1	05-09-2002

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